IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN *Ex rel.* CATHLEEN FORNEY Plaintiffs, vs. MEDTRONIC, INC., Defendant.	)	Case No. 5:15-cv-6264-EGS

DEFENDANT MEDTRONIC, INC.'S SUPPLEMENTAL MEMORANDUM IN FURTHER SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Before filing suit, Relator gave the Government a sizable stack of assorted Medtronic documents. Included within the reams of paper she produced were certain high-level Medtronic policies, various training materials, promotional materials describing Medtronic products and services, handouts with coding and reimbursement information, and low-resolution printouts of screenshots from various computer programs. By all accounts, Relator produced these documents to the Government the same way she provided them to the Court: as an undifferentiated document dump with no apparent organizational structure, and no explanation. To take stock of this, the Court ordered Relator to file a supplemental memorandum "identify[ing] specific documents . . . , contextualiz[ing] them, and explain[ing] how they materially add to the transactions and allegations of fraud disclosed in *Onwezen* and *Schroeder*." (Order at 2, ECF No. 74).

Relator's Supplemental Brief does the exact opposite: she takes the documents entirely out of context then selects small snippets of text—a phrase here, a bullet point there—to craft narratives that are contrary to what the documents plainly convey. In so doing, Relator's Supplemental Brief confirms what was already apparent from the face of the documents. None of these documents alleges or is indicative of wrongdoing. None of them evinces any false claims for payment. And none of them materially adds to the prior public disclosures in the *Onwezen* and *Schroeder* complaints. As a result, Relator does not qualify as an original source, and summary judgment should be entered for Medtronic.

PROCEDURAL POSTURE

On December 2, 2011, the United States District Court for the District of Minnesota unsealed a *qui tam* complaint filed against Medtronic by three co-relators led by Kathy Onwezen. (Onwezen Unsealing Order, Ex. D, ECF No. 64). The *Onwezen* complaint alleged

that the business model for Medtronic's cardiac rhythm division depended on offering and paying kickbacks in the form of device checks and other free services. (Onwezen Compl. ¶ 8, Ex. E,,ECF No. 64). Specifically, the complaint alleged that Medtronic protected and expanded its cardiac rhythm market share by promising physicians that if they implanted their patients with Medtronic devices, then Medtronic would provide, for free, "*substantially all device-related post-implant medical care*" for those patients. (*Id.* at ¶¶ 8, 68) (emphasis in original).

Consistent with that promise, Medtronic representatives allegedly conducted device checks wherever needed, including in physicians' offices, at device-check clinics, and in patients' homes. (*Id.* at ¶¶ 68, 72-74). The *Onwezen* complaint stated that the practice of providing free device checks was so pervasive that it was done for the "majority" of devices Medtronic implanted, and that Medtronic representatives performed up to 40 device checks per day. (*Id.* at ¶¶ 8, 78-82). The overarching goal of this supposed scheme, according to the complaint, was for Medtronic to be a "one-stop-shop," meaning that once a physician finished implanting a device, Medtronic would handle as much of the future care for the patient as possible, ideally obviating the need for the physician to even see the patient again. (*Id.* at ¶¶ 8, 70).

The *Onwezen* complaint further alleged that Medtronic representatives handled all aspects of the remote monitoring and billing processes associated with the devices they sold, including by completing all necessary paperwork so that physicians and their staffs would not need to. (*Id.* at ¶¶ 78-82, 95-104). Medtronic representatives also allegedly reviewed physicians' billing records and taught physicians how to maximize their reimbursement payments for procedures involving Medtronic's devices. (*Id.* at ¶¶ 75, 87-88).

The *Onwezen* complaint claimed that this company-wide scheme of conducting free device checks and providing free reimbursement consulting services had been ongoing since at least 1995, continued up through the present, and would continue into the future as patients continually needed post-implant device checks and other follow-up care. (*Id.* at ¶¶ 3, 76).

On May 27, 2014, the United States District Court for the Eastern District of California unsealed a *qui tam* complaint filed against Medtronic by relator Adolfo Schroeder. (Schroeder Unsealing Order, Ex. H, ECF No. 64). Schroeder alleged that Medtronic used kickbacks, including in-kind services, to differentiate itself from its competitors, since Medtronic's cardiac rhythm devices "were not superior to other similar devices made by other companies on the market." (Def. Mot. Summ. J., Schroeder Compl. ¶ 7, Ex. I, ECF No. 64). Schroeder alleged that the in-kind services Medtronic offered consisted of reimbursement advice and practice management consulting, both of which were intended to increase physicians' profitability. (*Id.* at ¶¶ 51, 74-75, 81).

Regarding reimbursement advice, Schroeder alleged that Medtronic representatives taught physicians how to bill Medicare, Medicaid, and private insurers for the purpose of increasing sales of Medtronic's devices. (*Id.* at ¶¶ 51, 74). To that end, Medtronic allegedly incorporated the provision of free reimbursement advice into its business plans and sales pitches. (*Id.*) Medtronic also allegedly developed and distributed written reimbursement materials to facilitate this supposed scheme. (*Id.* at ¶ 73).

Regarding business consulting, Schroeder alleged that Medtronic taught physicians how to manage their practices efficiently and profitably. (*Id.* at ¶¶ 73, 81). Medtronic allegedly distributed free instructional guidebooks that conveyed this advice. (*Id.*). Medtronic representatives also allegedly promoted a "turn-key heart failure clinic business solution," which

taught cardiologists and hospitals how to use Medtronic's pre-printed forms, templates, and guides to operate clinics. (*Id.* at ¶ 81). In other words, Schroeder alleged that Medtronic representatives provided comprehensive business consulting, for free, to induce sales of Medtronic devices.

In light of these significant public disclosures, the Court indicated in its Order dated April 3, 2018, that the *Onwezen* and *Schroeder* complaints are sufficient to trigger the False Claims Act's public disclosure bar here. (Order at 2). The Court further ordered the parties to brief whether the documents Relator produced first to the Government and later to the Court qualify her as an original source.

ARGUMENT

Relator does not come close to qualifying as an original source as to either the device check or free business consulting services theories that *Onwezen* and *Schroeder* first alleged. In order to have standing to continue this case, Relator would have needed to disclose to the Government before filing suit information that adds in a significant way to the essential factual background of the publicly disclosed allegations of fraud. The information Relator produced, however, was an unremarkable stack of Medtronic documents that reflected routine business operations. These documents do not add significant facts to the schemes *Onwezen* and *Schroeder* disclosed, nor even say on their face what Relator claims in her Supplemental Brief. These documents would not have a natural tendency to move the Government to action in light of the prior public disclosures, and indeed did not do so. They are immaterial here as a matter of law, and Medtronic's Motion for Summary Judgment should be granted as a result.

I. Controlling Precedent Sets a High Bar for Qualifying as an Original Source Here

When, as here, the public disclosure bar is triggered, a *qui tam* relator can clear the bar and avoid dismissal of her case only if she qualifies as an original source. 31 U.S.C. §

3730(e)(4)(A). The statute defines an "original source" as one "who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section." *Id.* at (e)(4)(B).

The leading case in the Third Circuit on what it means to "materially add" to a prior public disclosure is *United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294 (3d Cir. 2016). In Moore, the Third Circuit held that a relator qualifies as an original source if the information she provided to the government before filing suit "contribute[s] significant additional information to that which has been publicly disclosed so as to improve its quality." *Id.* at 306. For further guidance on distinguishing the material from the immaterial, the Third Circuit looked to Rule 9(b)'s pleading requirements and concluded that information "materially adds" to a prior public disclosure if it "adds in a significant way to the essential factual background: 'the who, what, when, where, and how' of the events at issue." *Id.* at 306-07.

Since the Third Circuit decided *Moore* in February 2016, there has been additional, controlling precedent on the meaning of the term "material" within the context of the FCA. Four months after the Third Circuit issued its decision in *Moore*, the Supreme Court decided *Universal Health Servs. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016). In *Escobar*, the Supreme Court held that, "[u]nder any understanding of the concept, materiality looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Id.* at 2002 (internal quotation marks and alterations omitted). Although *Escobar* was interpreting the term "material" as it is used in the liability provisions of the FCA, *Escobar*'s definition of "material" is equally applicable to the public disclosure bar because, as both the Supreme Court

and the Third Circuit have held, materiality is a unitary concept; it always has the same meaning. *Id.*; *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 763 (3d Cir. 2017).

Following *Escobar*, a relator "materially adds" to a prior public disclosure if the new information she provided to the Government before filing suit would have a "natural tendency to influence" the Government's decisions. *See* 136 S. Ct. at 2002; *United States ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201, 211 (1st Cir. 2016) (applying *Escobar* to the original source provision of the public disclosure bar). This is a "rigorous" requirement. *Escobar*, 136 S. Ct. at 2002, n.6. It is also, by necessity, a comparative inquiry that evaluates the significance of the new information against the totality of the prior public disclosures. *See Winkelman*, 827 F.3d at 211 ("As the level of detail in public disclosures increases, the universe of potentially material additions shrinks."); *United States ex rel. Freedom Unlimited, Inc., v. City of Pittsburgh*, 2:12cv1600, 2016 WL 1255294, at *23-24 (W.D. Pa. Mar. 31, 2016), *vacated*, 17-1987, 2018 WL 1517159 (3d Cir. Mar. 28, 2018) (remanding the public disclosure bar ruling for development of factual record and summary judgment, and vacating on other grounds) (following *Moore* and comparing relator's new information "against the backdrop of information that cumulatively was [publicly] disclosed" before relator filed suit).

Although *Moore* was decided before *Escobar*, the reasoning in *Moore* fits within the framework for materiality that *Escobar* establishes. In *Moore*, the theory of liability was that the defendants fraudulently obtained fishing licenses by falsely claiming that U.S. citizens controlled certain LLCs and captained certain fishing vessels. 812 F.2d at 296. The qualifying public disclosures consisted of two unrelated news articles published on the internet suggesting foreign control of the LLCs and foreign command of the vessels, as well as separate FOIA documents showing defendants' representations that U.S. citizens were at the helm of each company and

each ship. *Id.* at 301-04. The court held that when pieced together, these disparate sources were sufficient to raise an inference of fraud and thereby trigger the public disclosure bar. *Id.* at 303-04.

The relator in *Moore* qualified as an original source by providing voluminous additional facts. *Id.* at 306. Before commencing the *qui tam* action at issue in *Moore*, the relator sued the defendants in a separate wrongful death action. *Id.* Drawing on the extensive information that the relator learned through civil discovery in that earlier case, the relator disclosed specific details as to how the fraud was conducted, including the identities of the foreign nationals who truly controlled the LLCs and the vessels, the details of the sham transactions used to hide their true ownership stakes, and that a fictitious "manager" of the LLCs initiated the applications for the fishing licenses. *Id.* at 307-08. The prior public disclosures revealed the skeletal outline of a potential fraud. The new information that the relator provided put meat on the bones, detailing the precise "who, what, where, when, and how" of the gravamen of the scheme. *Id.* at 307.

Together, *Moore* and *Escobar* set a high bar for Relator to qualify as an original source here—one she does not come close to clearing. Unlike the public disclosures at issue in *Moore*, the disclosures here were not a limited assortment of puzzle pieces that, when correctly assembled, gave rise to an *inference* of fraud. The disclosures here were direct allegations of fraud in detailed complaints that were served on, and prompted investigation by, the Government. (Pl.'s Opp. to Mot. Summ. J., Ex. 5; Ex. 6, ECF No. 69,). After completing its investigations, the Government intervened in both cases and settled with Medtronic as to allegations other than the device check and consulting services theories.[1] (*Id.*) Given the nature

[1] Relator's argument that these prior settlements demonstrate that Medtronic knowingly paid kickbacks in the form of free services misrepresents the settlement documents. In the settlement agreement, the Government did not allege that device checks or free consulting services constituted illegal remuneration or were part of the conduct covered by

and extent of these prior public disclosures, to significantly add to those disclosures in a way that would be sufficient under *Moore*, Relator would need to have added significant facts that show something critical for the first time about the heart and workings of the alleged scheme. *See Moore*, 812 F.3d at 307-08. It is this sort of information that would have a "natural tendency to influence" the decision the Government faced when evaluating the documents Relator produced—that is, the decision whether to re-open an investigation and/or to intervene in the case. *See Escobar*, 136 S. Ct. at 2002 (holding that materiality is to be assessed from the standpoint of the relevant decision-maker with respect to the decision at hand). Because Relator did not provide the Government with information of that kind or quality, as evidenced, in part, by the Government's lack of further action in response to her disclosures, she does not qualify as an original source, and judgment should be entered for Medtronic. *See id.* at 2003-04 (holding that the Government's failure to act is strong evidence against materiality).

II. Relator Forney Is Not an Original Source as to the Device Check Theory.

A. Viewed in their Entirety, the Documents Relator Provided to the Government Do Not Materially Add to the Allegations in *Onwezen*.

At its core, the *Onwezen* complaint alleged that Medtronic's entire cardiac rhythm business model was based on the payment of in-kind kickbacks in the form of device checks and other post-implant services. According to *Onwezen*, the principal players in this scheme—the "who," as *Moore* puts it—were Medtronic's entire field sales force. (*See* Onwezen Compl. ¶¶ 8, 68, 78-82, Ex. E, ECF No. 64). The "where" was nationwide. (*See id.*) The "when" was an ongoing practice dating back more than a decade and continuing into the foreseeable future. (*Id.* at ¶¶ 3, 76). The mechanics of the alleged scheme—the "what" and the "how"—was to offer a

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the agreement. (Pl.'s Opp. to Mot. Summ. J., Ex. 5 at 2, ECF No. 69,). If anything, these prior settlements indicate that Relator is opportunistically pursuing a theory that the Government itself has declined to endorse.

comprehensive, soup-to-nuts process of handling all post-implant follow-up care, billing, and paperwork for all implanted devices. (*Id.* at ¶¶ 8, 70).

Nothing Relator disclosed to the government before filing suit materially adds to the picture of the alleged scheme painted by the *Onwezen* complaint. In her Supplemental Brief, Relator points to computer printouts of device check schedules, a handful of emails and voicemail transcripts in which device checks are discussed, and printouts from Google Calendar. (Pl.'s Supplemental Br. at 8-13, ECF No. 75). Relator argues that these documents show "who" was conducting device checks (the individuals named within them), on whose behalf the device checks were conducted (the hospitals named), and "where" and "when" device checks occurred. (*Id.*) At best, these documents collectively indicate that the company-wide practice of conducting device checks, which was publicly alleged by *Onwezen*, also occurred in Eastern Pennsylvania, and was carried out by the specific field representatives who worked there. These micro-level details do not materially add to the macro-level description of fraud that *Onwezen* publicly disclosed, because they are fully anticipated and encompassed by *Onwezen*: an alleged scheme involving the entire, company-wide field sales force logically encompassed Eastern Pennsylvania and the specific people who worked there. *See Winkelman*, 827 F.3d at 212 (holding that relator did not qualify as an original source because allegations of (1) specific instances of the same alleged scheme, and (2) new states in which the same scheme allegedly occurred were not material additions); *United States ex rel. Zizic v. Q2Administrators, LLC*, 728 F.3d 228, 238 (3d Cir. 2013) (holding that, under the pre-PPACA public disclosure bar, revealing the identity of the person responsible for executing a fraudulent scheme was insufficient to clear the bar in light of prior disclosures of the mechanics of the fraud); *cf. Moore*,

812 F.3d at 307-08 (holding that relator qualified as an original source because it revealed the precise, previously undisclosed mechanics of how the fraudulent scheme was implemented).

Relator nevertheless devotes a significant portion of her Supplemental Brief to cataloging the names printed on the documents she provided to the Government before filing suit. (Pl.'s Supplemental Br. at 8-13). Relator's position appears to be that each name constitutes a chit added to the "who" bucket, and that the total number of chits must amount to a material addition. Unlike the Relator in *Moore*, who used civil discovery to uncover the undisclosed mechanics of the fraud and reveal the identities and roles of the previously unknown principals in the conspiracy, 812 F.2d at 307-08, Relator is merely pointing to anyone and everyone who worked in the field for Medtronic's cardiac rhythm business. This cumulative evidence showing that many people worked for Medtronic does not add "in a significant way to the essential factual background." *Id.* at 307 (emphasis added).

The absurdity of this exercise of treating each and every name as significant is aptly demonstrated by Relator's reliance on a letter offering a Principal Clinical Specialist position to Richard C. (Pl.'s Supplemental Br. at 10) (citing REL-0682). The trivial fact that Richard C., whoever he is, was offered a job as a clinical specialist is not material as a matter of law, because it would not have any bearing on the Government's decisions as to whether to intervene in this case or to investigate Relator's allegations. *See Escobar*, 136 S. Ct. at 2002. *Onwezen* had already publicly disclosed that every clinical specialist at Medtronic was offering to perform device checks. That one of the clinical specialists was named Richard is simply irrelevant. By that same token, the identities of other people who worked for Medtronic's cardiac rhythm business in Eastern Pennsylvania are equally immaterial in light of the bread of disclosures in *Onwezen*.

At other points in her Supplemental Brief, Relator argues that the documents she provided to the Government are material additions because they pertain to later points in time than the allegations in *Onwezen*. (Pl.'s Supplemental Br.at 8). This is also a dead end. In *Winkelman*, the leading case interpreting the public disclosure bar post-*Escobar*, the public disclosures established that the pharmacy chain CVS took the position that certain price discounts did not need to be reported to Medicaid. 827 F.3d at 212. The relators argued that they qualified as original sources because their allegations established that CVS continued to hold that position later in time than had previously been disclosed. *Id.* The court summarily rejected this argument, holding that the prior public disclosure gave "every reason to think that CVS's scheme would [continue] past the date" of the prior disclosures. *Id.* Here, the fact that the prior public disclosures gave every reason to think that Medtronic would continue to provide device checks is even stronger, since the *Onwezen* complaint alleged free device checks were a core business practice of the cardiac rhythm division that had been ongoing for years, was still ongoing, and would last the lifetime of the implanted devices. (Onwezen Compl. at ¶¶ 3, 76). This was not just a strongly held corporate position, as the public disclosures in *Winkelman* were, but supposedly part of the cardiac rhythm divisions' daily operations. As a result, Relator does not materially add to the *Onwezen* disclosures by extending the timeframe by a few years. *See Winkelman*, 827 F.3d at 212*; United States ex rel. Judd v. Quest Diagnostics Inc.*, 638 Fed. App'x 162, 168 n.7 (3d Cir. 2015) (holding that relator did not materially add to prior public disclosures by alleging that the fraud continued); *United States v. Medco Health Sols., Inc.*, CV 11-684-RGA, 2017 WL 4838410, at *6 (D. Del. Oct. 26, 2017) (following *Moore* and *Judd*, and holding that relator did not materially add to prior public disclosures by alleging that conduct continued). Relator does not cite any cases to the contrary.

Relator also does not advance her cause by claiming that the documents she produced to the government corroborate the device check allegations that *Onwezen* publicly disclosed. As a threshold matter, the documents Relator gave the government do not corroborate *Onwezen's* allegations. As discussed more fully in Section II.B., below, these documents do not show that device checks were actually performed by Medtronic representatives as an inducement to purchase Medtronic's products. They do not show management instructing representatives to conduct device checks for that purpose. Nor do they contain any payer or billing information from which one might infer that claims were submitted to government healthcare programs. What the documents actually show are device check schedules and incidental discussions of device checks. At best, this meager evidence is generally consistent with what *Onwezen* alleged; it is not corroborative. Regardless, even if these documents were corroborative, Relator still would not qualify as an original source, because information that confirms or corroborates a publicly disclosed allegation is not a material addition. *See Winkelman*, 827 F.3d at 213.

B. The Documents Relator Forney Provided to the Government Are Vague and Irrelevant, Not Material Additions to the Device Check Theory *Onwezen* Disclosed.

As the foregoing demonstrates, the documents Relator provided to the Government before filing suit do not constitute material additions to the comprehensive allegations publicly disclosed by the *Onwezen* complaint. That analysis alone is sufficient to warrant the conclusion that Relator does not qualify as an original source as to the device check theory. But the deficiencies with Relator's pre-filing production to the Government run deeper still. In particular, these documents do not on their face support either Relator's theories of liability or the assertions she makes about their contents in her Supplemental Brief.

1. Computer Screenshots

Relator characterizes the various computer printouts she produced to the Government as a

"treasure trove of material information about the details regarding Medtronic's actual payment of kickbacks." (Pl.'s Supplemental Br. at 7). A cursory review of these documents reveals them to be anything but that.

The first set of documents Relator points to is a collection of data sheets, primarily from implant surgeries, that is interspersed with screenshots of schedules purportedly from the Dropbox computer program. (*See* Pl.'s Supplemental Br. at 9-11). Relator argues that a schedule Bates-stamped REL-02254 shows that "Medtronic representative Chuck Mertz conducted a device check clinic" at "Quakertown" and "Windgap" on various dates for various numbers of patients. (*Id*. at 9).

But this document does not say any of those things. The name Chuck Mertz does not appear anywhere on the document. (*See* Pl.'s Opp. to Mot. Summ. J., Ex. 17 at REL-02254). The document does not say anything about device check clinics at either Quakertown or Windgap. (*Id*.) The document does say that device checks were scheduled at Windgap, but there is no indication of who conducted those device checks, or even whether they were actually performed, as opposed to merely scheduled. (*Id*.) There is no mention of device checks at all at Quakertown, just time slots and associated patient tallies. (*Id*.) Relator further states that this document lists the names of four patients who had their devices checked at Quakertown, (Pl's Supplemental Br. at 9), but there is nothing on the face of this document identifying the individuals named as patients or specifying that they were scheduled to have their devices checked, (Pl.'s Opp. to Mot. Summ. J., Ex. 17 at REL-02254). The second example of a similar schedule that Relator cites—REL-02257-02258—suffers from the exact same deficiencies.

The other documents from this set are similarly unhelpful to her cause. Relator claims that the documents marked REL-2264, -2265, -2270, and -2272, "establish Marla Lyon provided

free services at St. Luke's." (Pl.'s Supplemental Br. at 10). Each one of those documents, however, is a data sheet that appears to relate to an implant surgery, not a device check. Each one lists the "Location of Surgery," the "Date of Surg[ery]." and the "Implanting Phys[ician]." (Pl.'s Opp. to Mot. Summ. J., Ex. 17 at REL-2264-65; -2270; -2272). Relator is not pursuing the theory that attending an implant surgery constitutes a kickback, (see Pl.'s Supplemental Br. at 10, n.2), so these documents are completely irrelevant to the claims that remain in this case.

It is theoretically possible that Relator or some other witness could have provided additional information about these documents. That would only be relevant, however, if before filing suit Relator had in fact provided such information to the Government along with the documents. *See* 31 U.S.C. § 3730(e)(4)(B). But that is not what happened. Instead, as Relator's own declaration establishes, she produced a stack of documents with no explanation or accompanying testimony. (Pl.'s Opp. to Mot. Summ. J., Ex. 16 at ¶ 5, ECF No. 69). These documents are not only immaterial given the broad disclosures in *Onwezen*, they are effectively worthless in the form in which they were produced.[2]

2. **Emails and Voicemail Transcripts**

The only communications Relator produced to the Government before filing suit is a small collection of emails and rough transcripts of voicemails. (See Pl.'s Opp. to Mot. Summ. J., Ex. 17 at REL-02271-74; -01418-01458). None of these documents show Medtronic conducting device checks as a form of in-kind remuneration.

Several of the emails Relator cites are requests, possibly from providers although that is not always clear, for assistance with device checks or other post-implant procedures. (*See id*. at

[2] As discussed in Section II.A., above, even if Relator or another witness had provided explanations of these documents, she still would not qualify as an original source, since specific examples of device checks do not materially add to the contours of the fraud alleged by *Onwezen*.

REL-01419, -01421, -01422, -01426, -01451). There are no indications on the face of these documents that those requests were granted. Nor is there any indication that the requests themselves were improper. There is, for example, no suggestion of any *quid pro quo*.

This is particularly significant because a number of the documents Relator cites suggest completely innocent explanations, even under Relator's theory, for why Medtronic's assistance may be needed with a particular device check or another form of product support. For example, one email asks for help because a Carelink unit was not transmitting data. *Id.*, Ex. 17 at REL-01424; -01429. As another example, one voicemail transcript, Ex. 17 at REL-01419, seems to ask whether the attendance of a Medtronic representative was needed in connection with a surgery unrelated to the patient's device, similar to how Medtronic representatives attended implant surgeries. The caller explains that a patient with a Medtronic pacemaker/defibrillator was scheduled for a total knee replacement. (*Id.*) The caller then asks whether the voicemail recipient "need[s] to come in for that[, or] if we can just But AM back now and then or whatever [sic]." (*Id.*) To the extent this transcript is even intelligible, it appears to ask whether the Medtronic pacemaker/defibrillator patient's knee replacement surgery required the attendance of a Medtronic representative. This was a request for information pertinent to a patient's medical procedure, not the solicitation of a kickback. And there is not even any indication as to what the Medtronic representative said in response.

In sum, Relator provided to the Government a smattering of emails and voicemails regarding device checks. None of those documents suggests on its face an improper purpose for the checks, while a few appear to describe conduct that Relator takes no issue with at all. (*See* Tr. of Oral Arg. at 47:19 – 48:25, ECF No. 46) (conceding that responding to requests for technical support does not constitute remuneration). These documents muddy Relator's own

case. They do not materially add to the broad, detailed allegations publicly disclosed by *Onwezen*.

3. **Google Calendar Documents**

As with the initial round of briefing and oral argument, Relator once again contends that the printouts of Google Calendar records from her Eastern Pennsylvania district materially add to the prior public disclosures. These documents, however, contain very little information. The Google Calendar entries show only when device checks were scheduled. They do not show whether any particular device check was performed, and as Relator admitted at her deposition, she does not know whether any of these procedures were performed. (*See* Def. Mot. Summ. J., Ex. L, Forney Tr. 244:8 – 245:18, ECF No. 64). Further, like all of the other documents Relator gave the Government, the Google Calendars contain no information whatsoever regarding payers or claims for payment. These arguments as to the immateriality of the Google Calendars featured prominently during the initial round of briefing and at oral argument, yet Relator offers no answer to them in her Supplemental Brief.

Instead, Relator, for the first time, asserts that the Google Calendars contain "material information about how Medtronic ran clinics." (Pl.'s Supplemental Br. at 12) (citing Ex. 17 at REL-01683-686). The calendars contain no such explanatory information. As they do with device checks, the calendars merely indicate when clinics were scheduled. (*See*, e.g., Ex. 17 at REL-01683). They do not state that a Medtronic representative ran or even attended any clinic—much less provide a narrative as to how device clinics operated. *(Id.)*

4. **Performance Evaluation Criteria and Compensation Plans**

Relator claims that the few performance evaluation and compensation plan documents she produced show that "Medtronic evaluated and compensated Medtronic sales staff in ways that financially incented sales staff to promote constantly the kickbacks ('services') to physicians

and hospitals." (Pl.'s Supplemental Br.at 2). Once again, the documents themselves bear no resemblance to Relator's characterizations. And it is the document's themselves, not Relator's counsel's self-serving characterization of them, that matters here. *See, e.g.*, *Thornton v. United States*, 493 F.2d 164, 167 (3d Cir. 1974) ("A statement in a brief or in oral argument does not constitute evidence."). The clinical specialist performance management guide that Relator produced sets forth the expectations that clinical specialists provide product support during implant surgeries, "troubleshoot all devices competently and effectively," and "[e]ducate[] and train physicians, hospital personnel, and office staff on technical matters relating to our products and therapies." (Pl.'s Opp. to Mot. Summ. J., Ex. 17 at REL-01238). Relator quotes one bullet point from this document that states representatives should "translate customer needs into Medtronic solutions." (*Id*. at REL-01240). Nothing in this document elaborates on what, precisely, that means, but in light of the whole document there is no reason to conclude it means anything other than serving as an effective ambassador and promoter for the company.

Relator claims that the compensation plans she produced incented representatives to offer kickbacks in the form of free services, yet she does not even bother to explain her theory as to why that is so. (Pl.'s Supplemental Br. at 18-19). The documents themselves, of course, say nothing about offering free services to induce purchases. (See Pl.'s Opp. to Mot. Summ. J., Ex. 17 at REL-0590-651). Nor do the "sales contest" documents she cites draw any connection between device checks and sales. (*Id*. at REL-00642-45; REL-01872-74).

III. Relator Forney Is Not an Original Source as to the Consulting Services Theory.

Collectively, the *Onwezen* and *Schroeder* complaints alleged that Medtronic provided two types of consulting services as a form of in-kind remuneration. First, both complaints alleged that Medtronic representatives provided physicians with advice and assistance regarding billing and reimbursement. Second, *Schroeder* additionally alleged that Medtronic provided

extensive business management consulting services for free. The documents Relator produced to the Government do not materially add to these disclosures.

A. Relator Does not Materially Add to the Publicly Disclosed Allegation that Medtronic Provided Free Reimbursement Services.

The documents Relator produced to the Government regarding Medtronic's alleged reimbursement services were an assortment of pamphlets and instructional booklets listing the billing codes for Medtronic's devices. (*Id*. at REL-00001-133; REL-00270-406). Putting aside the point that HHS-OIG has advised that companies can provide reimbursement advice like this for free because it has "no substantial independent value" to the purchaser, HHS-OIG Compliance Program Guide (2003) at 19, none of these documents added in any way to the prior public disclosures. *Schroeder* specifically alleged that Medtronic developed and distributed written reimbursement materials. (Def. Mot. Summ. J., Schroeder Compl. at ¶ 73, Ex. I). For its part, *Onwezen* claimed that Medtronic's reimbursement practices went far beyond distributing coding booklets like those Relator produced. According to *Onwezen*, Medtronic representatives provided personalized billing advice to physicians and actually completed billing paperwork. (*Id*., Onwezen Compl. at ¶¶ 78-82, 87-88, 95-104, Ex. E). Relator's production of these reimbursement guides to the Government merely rehashed a portion of what was already publicly alleged. It thus fell far short of being a material addition. *See Winkelman*, 827 F.3d at 212 ("Offering specific examples . . . does not provide any significant new information where the underlying conduct has been publicly disclosed.").

Perhaps sensing that these reimbursement guides do not help her clear the public disclosure bar, Relator argues in her Supplemental Brief that a slide deck she produced regarding new Medicare codes reveals a previously undisclosed aspect of the supposed scheme. Specifically, she argues that Medtronic instructed sales representatives to conduct device checks

only when physicians were present in the office so that the physicians could claim that they exercised "direct supervision" over the check and could thus bill Medicare for it. (Pl.'s Supplemental Br. at 19-20).

There are two insurmountable problems with this argument. First, the slide deck she produced does not say anything at all about Medtronic representatives conducting device checks, or what supervision requirements they should follow when doing so. (*See* Pl.'s Opp. to Mot. Summ. J., Ex. 17 at REL-01169). The deck merely explains the new Medicare codes and the supervision requirements that must be followed, according to Medicare program rules, in order for physicians to bill those codes. (*Id.*)

Second, the theory that Medtronic representatives conducted device checks so that physicians could bill more money to Medicare is not a theory that Relator has alleged in this case. Not one of the three complaints that she filed alleges that physicians billed Medicare for services that Medtronic performed, or that device checks otherwise enabled physicians to increase their Medicare billings. Her theory has consistently been that free device checks saved physicians the hassle and expense of conducting the checks themselves or with their own staff. (*See, e.g.*, Second Amended Complaint, ¶ 1, ECF No. 42). The only connection she alleged between the supposed kickbacks and Medicare billing was the claim that receipt of the alleged kickbacks caused physicians to falsely certify their compliance with the Anti-Kickback Statute when they submitted claims for payment. (*Id.* at ¶ 2). Relator cannot amend her complaint in a supplemental brief in support of summary judgment. *See OTA P'ship v. Forcenergy, Inc.*, 237 F.Supp.2d 558, 561 n. 3 (E.D.Pa.2002) (holding that a new claim that was first raised in opposition to a motion for summary judgment was "too late"). Nor can she be an original source as to a theory she has not brought.

B. Relator Does Not Materially Add to the Publicly Disclosed Allegation that Medtronic Provided Free Business Management Consulting Services.

In one short section of her Supplemental Brief, Relator argues that the assortment of consulting-related documents she provided to the Government disclosed materially new information about Medtronic's alleged practice of providing free business consulting services. (Pl.'s Supplemental Br. at 13). A quick review of each document she cites demonstrates that not one of these documents told the Government anything about any free services. As a result, they do not even support Relator's theory, let alone materially add to the allegations disclosed in *Schroeder*.

Relator first argues that the two "Lean Sigma" pamphlets she produced to the Government are material additions because they revealed the identities of the consultants who provided free "Lean Sigma" business management consulting services. (*Id*. at REL-01773-87). Although one of the pamphlets does identify a roster of consultants, neither pamphlet says anything whatsoever about free consulting services. To the contrary, both pamphlets refer to the clients for these consulting engagements as "customers," strongly implying that the services rendered were not free. (*Id*. at REL-01773; -01777). That inference is amplified by the overall appearance of these pamphlets, which suggests that they are marketing materials used to sell consulting services. That Medtronic undertook paid consulting work is demonstrated by another document Relator produced to the Government and cited in her brief, REL-00521, which advertises "business intelligence and strategic insights" as part of the "fee-based service" called HEARTmark. (emphasis added).

Relator's counsel argues that the documents Bates-stamped REL-00471-484; -00492-508 are "worksheets created for free by Medtronic." (*Id*. at 13). But, as with so many of the documents Relator produced, there is nothing in either document that identifies it as such. In any

event, *Schroeder* previously disclosed the allegation that Medtronic provided worksheets and templates to hospitals, (Def. Mot. Summ. J., Schroeder Compl. at ¶ 81, Ex. I), so even if these documents did show on their face that there were consulting services provided for free, that still would not add anything material to the public disclosures from *Schroeder*.

Finally, Relator argues that she gave the Government examples of hospital credentialing agreements and the names of the senior managers involved in the alleged consulting services scheme. (Pl.'s Supplemental Br. at 13-14) (citing Ex. 17, REL-2512-14, REL-02515-17, REL-02520, REL-02991, REL-02292-95). However, that assertion is contradicted by Relator's own declaration, which indicates that those documents were not included in her production to the Government. (*See* Pl.'s Opp. to Summ. J., Ex. 16, Decl. of Cathleen Forney) (stating that the production to the Government ended at Bates number REL-02274). Since these documents were not given to the Government before Relator filed suit, they cannot qualify her as an original source. *See* 31 U.S.C. § 3730(e)(4)(B).

IV. The "Value Based Service" Materials Do Not Materially Add to the Publicly Disclosed Allegations of Device Checks or Free Consulting Services.

In her Supplemental Brief, Relator leans heavily on excerpts from several "Value Based Service" (VBS) workbooks to argue that she materially added to the "what" and "how" of the alleged device-check and free-consulting-services schemes. (Pl.'s Supplemental Br. at 14-18). There are two fatal defects with this argument. First, all of the VBS documents were dated in either 2006 or 2008, two to four years before the time period at issue in this case. (*See* Pl.'s Opp. to Summ. J., Ex. 17 at REL.-01916; -02017; -02147). Nothing in the materials that Relator provided to the Government indicates that these documents were in use at any point after March 2010, which is as far back as the conduct now at issue in this case extends. To the extent these documents provide evidence of anything, they are stale and legally irrelevant to

Relator's claims. *Cf. Stewart v. Rutgers, State Univ.*, 120 F.3d 426, 433-34 (3d Cir. 1997) (holding that evidence from outside the limitations period is admissible only if there is a logical connection to claims within the period). They therefore do not materially add to the prior public disclosures. Second, reading the VBS documents in context reveals that they are innocuous, do not support Relator's theories, and do not remotely reflect Relator's counsel's characterizations of them.

A. The VBS Workbooks Reflect Sales Communication Training, Not a Conspiracy to Pay Kickbacks.

The VBS workbooks, which are all copyrighted by the sales-training company Huthwaite, Inc. (*See* Pl.'s Opp. to Summ. J., Ex. 17 at REL.-01916; -02017; -02147), were intended to teach Medtronic representatives Huthwaite's trademarked "SPIN model" of sales communication, (*see id.)*. As the workbooks explain, "SPIN" is an acronym for "Situation Questions," "Problem Questions," "Implication Questions," and "Need-Payoff Questions." (*Id.* at REL-02030). The basic idea is that salespeople will be more effective if they use targeted questions to uncover customers' needs, and then propose solutions to those needs in the form of the products they are selling. (*See, e.g.*, *id.* at REL-02028) ("Huthwaite research has shown that **questioning** is a more persuasive approach for introducing the value of the product or service than **telling** the customer about the value.") (emphasis in original).

Situation Questions are used to learn basic information about the customer. (*Id.* at REL-02022). Examples include, "How many clinicians do you have on staff? How do you monitor your heart failure patients?" (*Id.)*. Problem Questions are used to uncover customers' dissatisfaction with some current state of affairs; for example, "Are you worried about the quality you get from your equipment?" (*Id.* at REL-02023). Implication Questions are used to "assist the customer in developing a better understanding of the consequences of [a problem]."

(*Id.* at REL-02026). As Huthwaite instructs, "[a]s a result of well-focused Implication Questions, the customer sees the problem as more important, and hence becomes more committed to finding a solution." (*Id.*). Need-Payoff Questions provide the customer with a framework for thinking about the solution, hopefully priming them to act on the solution the salesperson will soon propose. (*Id.* at REL-02028).

Once the salesperson has asked enough SPIN questions, they attempt to close the deal by selling the product's "Features," "Advantages," or "Benefits." (*Id.* at REL02032). For instance, a Medtronic salesperson might say, "The Medtronic Kappa® Family of pacemakers adapts pacing therapies to a patient's individual needs, providing personalized therapy and making pacemaker check-ups more efficient." (*Id.*)

The VBS materials consist of a pre-reading packet that summarizes the SPIN Model (*id.* at REL-02016-02037), a participant workbook with further instructions and exercises to test one's understanding of the concepts (*id.* at REL-02038-02102), and a roleplaying workbook evidently used to simulate sales situations, with one participant playing the seller and another playing the buyer, (*id.* at REL-01915-02015).

In sum, these documents reflect banal, consultant-driven, corporate sales training. No reasonable person would mistake them for the kickback guidebooks Relator's counsel breathlessly proclaims them to be. (*See* Pl.'s Supplemental Br. at 14-18).

B. Relator Takes Snippets of the VBS Workbooks Out of Context in a Failed Attempt to Show a Material Addition to the Prior Public Disclosures.

Relator's counsel's arguments regarding the VBS workbooks all follow the same pattern: first, she takes a quotation out of context; next, she extrapolates with florid flights of imagination about what that language might theoretically mean. Relator's first argument is that the VBS materials show that Medtronic management knew that they could not compete based on the

quality of their devices. She bases that assertion entirely on the statement that a "pervasive lack of perceived differentiation" is one of the challenges facing the cardiac rhythm market. (*See* Pl.'s Supplemental Br. at 14) (citing Ex. 17, REL02152). Not only is Relator's counsel's sweeping statement not supported by this single line of text taken out of context, but it is flatly contradicted by the remainder of the VBS materials. One of the primary objectives of the VBS program was to teach representatives how to *combat* the perceived lack of product differentiation by educating customers on the advantages of Medtronic's devices. After asking "SPIN" questions, representatives were instructed to teach customers about how the "Features," "Advantages," and "Benefits" of Medtronic's products would help solve a need they possessed. (*Id.* at REL-02032). Consistent with this objective, the materials speak at length about the clinical benefits of Medtronic's products (*id.* at REL-01919-20), state that Medtronic's mission is "[d]esigning, manufacturing, selling and supporting the highest quality, most reliable products we know how to make" (*id.* at REL-01922), and tout the state-of-the-art product innovations that Medtronic first brought to market, (*id.* at REL-01922-23). To say that the VBS documents show that Medtronic was competing based on free services rather than the merits of its products is simply wrong. Furthermore, *Schroeder* already alleged that Medtronic's cardiac rhythm devices "were not superior to other similar devices made by other companies on the market," (*see* Def. Mot. Summ. J, Schroeder Compl. ¶ 7, Ex. I), so even if one were to take Relator's counsel's tortured and completely inaccurate reading of the VBS materials at face value, she still would not be materially adding to the prior public disclosures.

Relator similarly claims that Medtronic acknowledged that it could not compete on price, by quoting a passage that discusses the "disadvantages of focusing on price when making decisions about medical devices." (Pl.'s Supplemental Br.at 14) (citing Ex. 17, REL-01964). As

the very next page of the exercise reveals, the larger point about pricing was that, unlike some other (unnamed) manufacturers, Medtronic does not simply "encourage the use of high-end devices in all situations." (*Id.*, Ex. 17 at REL-01965). Rather, Medtronic representatives use their expertise to recommend the right device for the right situation, which will save customers money over the long term. (*Id.*) Read in context, the language Relator's counsel quotes about the "disadvantages of focusing on price" means that there is more to consider than just the list price of each company's devices. It is not an instruction to provide free services in exchange for purchases.

Relator's counsel next abandons the text of the documents altogether and launches into a diatribe on the ensuing pages, claiming that because Medtronic could not compete on quality or on price, it had to resort to paying kickbacks in the form of free device checks. (Pl.'s Supplemental Br. at 14-15). Relator's counsel's musings on this topic are a work of pure fiction; they are not based on the actual content of the VBS materials.[3]

Relator concludes her discussion of the VBS materials by arguing that they taught sales representatives to reward customer loyalty while threatening to withdraw free services from physicians who "altered their buying behavior." (*Id.* at 18). None of the passages Relator cites even remotely supports this claim. She first cites a roleplaying exercise that says a hypothetical doctor "might miss out on valuable capabilities Medtronic offers" if he starts using a competitor's device. (*Id.*, Ex. 17 atREL-01945).[4] The document does not specify what those

[3] In the midst of her discussion of the Value Based Service materials, Relator cites an unrelated slide deck that provides a template for district meetings in Q4 FY11. (Pl.'s Supplemental Br. at 16) (Ex. 17, REL-01788-812). Relator argues that this document is "material evidence that Medtronic viewed the free services as the most important element of sales." (*Id.*) Her only support for that sweeping statement is one page in which the word "Service" appears "as the top bullet point of what was being sold." (*Id.*) Notably, this document says nothing whatsoever about device checks or free business consulting. No reasonable person would regard the word "service," by itself, to be material evidence of anything.

[4] Relator actually cites to REL-01922 in her brief, but the quoted language does not appear on that page. (Pl.'s Supplemental Brief at 18).

"capabilities" are, but the context provided by the rest of these materials suggests that it is a reference to the technical capabilities of Medtronic's products. Indeed, the very next paragraph discusses the advantages of Medtronic's remote follow-up technology, which allows a physician's office staff—not Medtronic representatives—to perform device checks over the Internet. (*Id.* at REL-01946). That paragraph notes that if the hypothetical doctor switched suppliers, she and her staff would need to spend more time doing device checks in person, because the competitor's technology does not allow for remote checks. (*Id.*) This passage discusses the drawbacks of using devices with inferior technology; it says nothing about punishing disloyal doctors.

Finally, Relator cites another roleplaying scenario that obliquely references Medtronic's expertise in helping physicians develop marketing plans. (*Id*. at REL-01951). This passage barely says anything at all; it certainly does not state or even imply that the help would be provided free of charge. This vague, passing reference to marketing assistance from a document written in 2006 is not even relevant evidence of the scheme Relator has alleged. *Cf. Stewart*, 120 F.3d at 433-34. It falls far short of being a material addition to the extensive, prior public disclosures.

CONCLUSION

For all of the foregoing reasons, Relator does not qualify as an original source, and summary judgment should be entered in favor of Medtronic.

Respectfully submitted,

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